MAY 2 9 2002

K021439

Section 6 510(k) Summary

Submitter: Animas Corporation, 590 E. Lancaster Avenue, Frazer, PA 19355

Contact: Michael J. Andrews, Ph.D., Director, Regulatory Affairs, Telephone: (610)-644 8990, extension 257, Fax: (610)-644-8717, Email: michaeland@animascorp.com

Name of Device: Animas Model R1000 IR Insulin Infusion Pump

Predicate Device: Animas R1000 Series Insulin Infusion Pump

Description of the Modified Device: The Animas Model R1000 IR Insulin Infusion Pump is an external syringe pump and delivery system that provides subcutaneous delivery of insulin for patients with diabetes mellitus who would benefit from a continuous insulin infusion process. The Model R1000 IR is used with an infusion set, e.g., the Animas ezSet™. The pump incorporates serial communications via an infrared (IR) interface. The Animas RS-232 IR serial interface adaptor (the "dongle"), the Animas R1000 IR cradle to hold the pump, the Animas and the Animas ezLink™ software for the user's personal computer are the remaining components of the system. The ezLink™ software will allow the user to download records from the pump for Daily Totals, Alarm History, Bolus History, as well as Basal Rate programs and PUMP Settings. A leather case and a belt clip are provided as accessories. The pump is intended for multiple years of use and the insulin syringe is a sterile, single use disposable manufactured for Animas.

The system will deliver a prescribed dosage of insulin as a single programmable bolus or at multiple programmable basal rates. The system will also provide set up information, dosage history, alarms, error and warning messages, device status, and self test capabilities.

Intended Use of the Modified Device: The intended use of the Animas Model R1000 IR Insulin Infusion Pump is the same as that of the Series R1000 Insulin Infusion Pump, namely to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in insulin dependent patients. The accessories to the Model R1000 IR, the Animas RS-232 IR serial interface adator (the "dongle"), the Animas R1000 IR cradle to hold the pump and the Animas ezLink™ software are intended to transfer data stored in the pump to the

personal computer of a patient or a physician, where it may be displayed, printed, and saved.

This device is intended for home use and is a prescription device.

Comparision of the Technological Features of the Modified Device and the Predicate Device: The modified device and the predicate (unmodified) device are nearly identical in terms of design, materials, and construction. The only difference is the addition of the short-range IR communication capability.

This difference between the modified device and the predicate device does not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2002

Mr. Michael J. Andrews
Director, Regulatory Affairs
Animas Corporation
590 East Lancaster Avenue
Frazer, Pennsylvania 19355

Re: K021439
Trade/Device Name: Animas Model R1000 IR Insulin Infusion Pump
Regulation Number: 880.5725
Regulation Name: Insulin Pump
Regulatory Class: II
Product Code: LZG
Dated: May 3, 2002
Received: May 6, 2002

Dear Mr. Andrews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8 Indications for Use Statement

510(k) Number: K021439

Device Name: Animas Model R1000 IR Insulin Infusion Pump

Indications for Use: The Animas Model Model R1000 IR Insulin Infusion Pump is intended to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the daily management of diabetes mellitus in insulin dependent patients. The accessories to the Model R1000 IR, the Animas RS-232 IR serial interface adator (the "dongle"), the Animas R1000 IR cradle to hold the pump and the Animas ezLink™ software are intended to transfer data stored in the pump to the personal computer of a patient or a physician, where it may be displayed, printed, and saved.

This device is intended for home use and is a prescription device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021439